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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/682,249	08/09/2001	Guerry L. Grune		1874

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GUERRY LEONARD GRUNE  
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EXAMINER

LAMM, MARINA

ART UNIT PAPER NUMBER

1616

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/682,249	<b>Applicant(s)</b> GRUNE, GUERRY L.	
	<b>Examiner</b> Marina Lamm	<b>Art Unit</b> 1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 January 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-25 and 27 is/are pending in the application.
- 4a) Of the above claim(s) 12-24 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-11 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/28/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/28/04 has been entered.
2. Claims pending are 1, 3-25 and 27. Claims 12-24 and 27 have been withdrawn from consideration. Claims 2, 26 and 28-48 have been cancelled. Claims 1, 4 and 7 have been amended.

### *Claim Objections*

3. Claim 3 is objected to because of the following informalities: Claim 3 depends from cancelled Claim 2. For the purpose of examination, Claim 3 has been interpreted as dependant from Claim 1. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Art Unit: 1616

Claim 7 as amended introduces new matter as it uses the phrase “inorganic sunblock agent has a primary particle size of less than 30 nm”. There is no support in the specification for this limitation. The limitation “inorganic sunblock agent has a primary particle size of less than 30 nm” was not described in the application as filed, and persons skilled in the art would not recognize in the applicant’s disclosure a description of the invention as presently claimed. The specification states that titanium dioxide, zinc oxide or combinations thereof can be used as inorganic sunscreens. Further, the specification discloses preferable diameter of *titanium dioxide particles* of less than about 300 nm. See [0068]. Further, original Claim 7 recites particle size of *titanium dioxide particles* of less than about 30 nm. However, neither specification nor original claims discloses the presently claimed particle size of other inorganic sunblock agents. Therefore, it is the examiner’s position that the disclosure does not reasonably convey that the inventor has possession of the subject matter of the amendment at the time of filing of the instant application.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language of Claim 4 is confusing because it is unclear whether or not the agents listed in lines 4-6 are additional ingredients of the composition.

***Claim Rejections - 35 USC § 102***

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 1, 4-6 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Lukenbach et al. (US 5,980,871).

Lukenbach et al. teach sunscreen compositions containing from about 2 to about 25% of an inorganic sunscreen agent such as titanium dioxide, zinc oxide or mixtures thereof, from about 0.5 to about 10% of an anionic emulsifier such as sodium stearate, and from about 0.5 to about 10% of an oil component comprising a carrier oil and an emollient. See Claim 16; col. 5, lines 15-67; col. 6, lines 1-36. The ratio of inorganic sunscreen agent to oil component is from about 0.3:1 to about 1:1. See Claim 27; col. 6, lines 37-40. The particle size of titanium dioxide particles is less than about 300 nm. See col. 6, lines 25-30. The Lukenbach's compositions have a pH of above 5 (for example, 6.42 or 7) and SPF of at least 10. See Claims 12-14; col. 6, lines 46-54; Examples 96 and 97. The compositions may additionally contain antimicrobial agents, depigmenting agents, anti-aging agents, etc. See col. 6, lines 61-65; Claim 19. The limitation "non-endocrine disrupting" in Claims 1, 4 and 8 is inherent in the compositions of Lukenbach et al. because the reference teaches the same ingredients as disclosed in the instant specification, i.e. zinc oxide, titanium oxide, sodium stearate, isopropyl PPG-2 isodeceth-7 carboxylate, etc. The compositions of Lukenbach et al. consist essentially of the same ingredients as the claimed composition.

Thus, Lukenbach et al. teach each and every limitation of Claims 1, 4-6 and 8-10.

*Claim Rejections - 35 USC § 103*

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. Claims 3 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lukenbach et al. in view of Strickland et al. (US 5,824,659).

Lukenbach et al. teach sunscreen compositions as discussed above. With respect to Claim 3, Lukenbach et al. do not teach aloe of the instant claims. However, Strickland et al. teach Aloe Vera (aloe barbadensis Miller) extracts containing cytoprotective oligosaccharides useful to protect skin from damaging effects of UV radiation. See col. 1, lines 11-15; Claim 1. The Aloe Vera gel of Strickland et al. is produced at low temperatures and “activated” under freezing temperatures. See col. 15, lines 29-33; col. 16, Example 1; col. 13, line 62. One of ordinary skill would have been motivated to employ aloe extract of Strickland et al. in sunscreen compositions of Lukenbach et al. with a reasonable expectation of beneficial results such as additional protection of the skin against UV light.

With respect to Claim 25, Lukenbach et al. teach a one-vessel process for making the sunscreen composition comprising first creating the water phase and then adding a carrier oil when the temperature of the water phase reaches a certain level, then adding an inorganic sunscreen agent and heating and mixing said resultant composition. See col. 8, lines 1-35. Although, the inorganic sunscreen is added after the addition of oil phase in the process of Lukenbach et al. (as opposed to before the addition of the oil phase in the instant claims), there appears to be no criticality associated with the order in which the ingredients are added.

Art Unit: 1616

12. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lukenbach et al. in view of Fardell et al. (WO 93/11742) supplied by the Applicant.

Lukenbach et al. applied as above. Lukenbach et al. do not explicitly teach inorganic sunblock agent having a primary particle size of less than 30 nm as claimed in the instant claim. However, Fardell et al. teach substantially transparent sunscreen compositions comprising a metal oxide, such as zinc oxide or titanium oxide, or both, having a mean primary particle size most preferably from about 15 nm to about 30 nm. See p. 2, lines 20-24; p. 7, lines 23-28. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sunscreen compositions of Lukenbach et al. such that to employ zinc oxide having a primary particle size of 15-30 nm. One having ordinary skill in the art would have been motivated to do this to obtain substantially transparent compositions that are "aesthetically pleasing to the user" as suggested by Fardell et al.

13. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lukenbach et al.

Lukenbach et al. applied as above. The reference is silent with respect to the IRF and NED of the composition. However, the sunscreen compositions of Lukenbach et al. contain the same ingredients as the claimed compositions (see above) and are used in skin care for the same purpose as the claimed compositions, i.e. for providing "adequate and safe protection for human skin." See col. 3, lines 60-63. Therefore, the determination of optimal IRF and NED of the composition by routine experimentation is obvious to one of ordinary skill in this art. There appears to be no criticality in the ratios since the prior art recognizes and obtains the same results. One having ordinary skill in the art would have been motivated to do this because the

Art Unit: 1616

reference demonstrates how to obtain the desired high sun protection and safety of the composition. No unexpected result is seen that would demonstrate an unusual result over the generic teachings of the "adequate and safe protection" in the reference.

***Conclusion***

14. No claim is allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (571) 272-0618. The examiner can normally be reached on Mondays, Wednesdays and Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached at (571) 272-0602.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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